

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 9-13, 15-18 and 30-38 were examined and rejected. Claims 1-8, 14 and 19-29 were previously cancelled.

No claim amendments are being made herein. Claims 9-13, 15-18 and 30-38 remain pending in the application.

Rejections Under 35 U.S.C. §103

In the Advisory Action, the rejection of claims 9-13, 15-18 and 30-38 under 35 U.S.C. §103(a) as being unpatentable over Kuehn et al. (USPN 6,165,183) in view of Cribier et al. (USPN 4,777,951) was maintained.

Claim 9, as well as claims 10-13, 15-8 and 30-38 by virtue of their dependency on claim 9, are directed to a method of repairing cardiac valves using an apparatus comprising a releasable fastener which is used to both temporarily grasp (step b) and permanently secure together (step e) the leaflets of a cardiac valve. The claimed method is further directed to determining whether to permanently secure valve leaflets at a selected apposition point based upon the measured blood flow and/or the pressure gradient through the valve when the fastener is temporarily grasping the valve's leaflets at the apposition point (step d).

In making this rejection, the Examiner makes reference to the disclosure in Kuehn et al (8:67-9:4) which states (with reference to Fig. 17) that “gripper 402 can grab leaflets 122, 124. Then, fastener 404 can be opened in the withdrawn position and slid forward to apply a tack on the captured leaflet edges.” The tack is shown illustrated in Fig. 17 but is not identified with a reference number. As such, Kuehn uses one mechanism to grasp the leaflets (grasper 402) and a separate mechanism (the tack) to permanently fasten the leaflets together. This system and its use are distinguishable from the claimed invention in at least three respects. First, Kuehn's grasper is not releasable from the apparatus which delivers and operates it (shaft 406). Second, Kuehn's tack is not capable of temporarily grasping the leaflets, only penetrating them. Finally, Kuehn et al. do not disclose using an apparatus having a fastener capable of performing both of the claimed temporary grasping and permanent securing functions, nor do Kuehn et al. disclose or recognize a need to temporarily grasp the leaflets.

Cribier et al. are cited for their teaching of measuring the pressure gradient across a valve during an aortic valvuloplasty which involves the use of an inflatable balloon to dislodge plaque from the valve leaflets. The balloon is repeatedly inflated and the pressure gradient measured between inflations until the gradient reaches a satisfactory value. Cribier et al. do not teach or suggest anything about applying fasteners or the like to valve leaflets and measuring across the valve to determine the effectiveness of the fastening site on the leaflet.

Neither Kuehn et al. nor Cribier et al. nor the combination thereof disclose, teach or suggest the claimed method. In particular, they do not disclose, teach or suggest a releasable fastener that is configured to both temporarily grasp and to permanently fasten leaflets together. Accordingly, Applicants respectfully request withdrawal of this rejection and allowance of the claims.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number CATT-001.

Respectfully submitted,
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